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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,177	03/19/2004	Gregory M. Landes	21402-665 (CURA 965)	8179

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EXAMINER	
NATARAJAN, MEERA	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
11/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,177	LANDES ET AL.	
	Examiner	Art Unit	
	MEERA NATARAJAN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 23-33* is/are pending in the application.

4a) Of the above claim(s) *13-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-12 and 23-33* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/21/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Abandonment mailed 03/18/2008 has been withdrawn in view of Applicant's petition filed 07/07/2009 which has been granted.

Election/Restrictions

2. Applicant's election of Group I, Claims 1-12 and 23-33 and species election "toxin" in the reply filed on 07/07/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 13-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/07/2009.

4. After further consideration the species requirement for therapeutic agent has been withdrawn. Claims 9 and 10 will be examined.

5. Claims 1-12 and 23-33 will be examined on the merits.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 3-12 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by McIntire et al. (PgPub 20030124114).

8. The claims are drawn to an isolated human antibody or binding fragment thereof that specifically binds to T cell, immunoglobulin domain and mucin domain 1 (TIM-1), wherein said antibody is conjugated to a therapeutic agent and a hybridoma cell line producing said antibody.

9. McIntire et al. teach T cell regulatory genes and there association with immune dysfunction. McIntire et al. disclose polymorphisms of TIM proteins including TIM-1, TIM-3 and TIM-4. McIntire et al. disclose binding agents, including nucleic acids and antibodies for functional studies such as diagnostics for assessing tumor resistance to cancer therapy. McIntire et al. disclose TIM blocking agents find use as therapeutics in the treatment of immune dysfunction and disorders of cell survival, including malignancies (see paragraph [0009]). McIntire et al. disclose the production of antibodies using hybridomas as well as genetic engineering. McIntire et al. disclose chimeric antibodies made through recombinant means in order to produce an antibody with human domains and the production of humanized antibodies (see paragraphs [0073-85]). McIntire et al. further disclose conjugated antibodies and antibody fragments. McInitre et al. disclose SEQ ID NO:87 of the instant application and therefore teach an isolated human antibody that specifically binds to a polypeptide comprising said sequence (see attached sequence alignment).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1, 3-12 and 23-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntire et al. (PgPub 20030124114) in view of Watkins et al. (PgPub 20040162413).

13. The claims are drawn to an isolated human antibody or binding fragment thereof that specifically binds to T cell, immunoglobulin domain and mucin domain 1 (TIM-1), wherein said antibody is conjugated to a therapeutic agent and a hybridoma cell line producing said antibody and a kit comprising said antibody. Claims 31-33 are drawn to an antibody or binding fragment thereof that specifically binds to the amino acid sequence of SEQ ID NO:87 and an isolated human antibody that binds to TIM-1 and is encoded by a VH3-33 germline with a Kd between 10-7 and 10-14M.

14. The teachings of McIntire are presented in the 102(e) rejection set forth above. McIntire et al. does not teach a kit comprising said TIM-1 antibody or an isolated human antibody encoded by the VH3-33 germline. These deficiencies are made up for by Watkins et al.

15. Watkins et al. teach method of optimizing antibody variable region binding affinity. Watkins et al. teach unvaried human frameworks such as VH3-33 which is used to help eliminate or reduce adverse immune responses when administered therapeutically in most individuals. Watkins et al. also disclose kits comprising a binding molecule (i.e. antibody) and instructions for using said binding molecule to treat a disease in a subject (see paragraph [0038]).

16. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the VH3-33 germline gene disclosed by Watkins et al. to optimize the TIM-1 antibody taught by McIntire et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Watkins et al. that optimizing the antibody helps eliminate or reduce adverse immune response effects. In addition it would be obvious to produce a kit comprising the TIM-1 antibody taught by McIntire et al. and instructions for the treatment of a subject because McIntire et al. disclose the TIM-1 antibody can be used for therapeutic purposes.

Conclusion

17. Claims 1, 3-12 and 23-33 are rejected.

18. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. SEQ ID NO:54 is free of the prior art.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643